## REMARKS

Examination on the merits is respectfully requested in light of the foregoing amendments and following remarks.

### 1. Status of the Claims

Claims 1-46 stand pending. The Office withdrawn Claims 1-16 stand withdrawn. Claims 17-46 stand rejected. Upon entry of the present amendments, Applicants cancel claims 1-16. Additionally, Applicants amend claims 17, 24, and 32-47 to more clearly and distinctly recite the subject matter. Support of claim amendments can be found at least, for example, in originally filed claims. Applicants submit that no prohibited new matter is introduced by entry of the present amendments.

Cancellation of and amendments to the claims have been made without prejudice to or disclaimer of the subject matter contained therein. Applicants reserve the right to file a continuation and/or divisional on any subject matter canceled by way of amendment.

### 2. Priority Documents

Applicant respectfully request acknowledgement of the certified priority documents submitted on January 23, 2006 with the Office's next communication.

### 3. Acceptance of Drawings

Applicant respectfully request status as to the acceptance of the drawings as filed with the Office's next communication.

### 4. Acknowledgement of Information Disclosure Statement

Applicants note with appreciation the acknowledgement of the Information Disclosure Statements filed January 23, 2006; March 26, 2007; and February 4, 2009.

## 3. Finality of Restriction / Election Requirement

Applicants note that the Restriction / Election Requirement has been made final. Applicants reserve the right to file a Petition on the Office's position regarding Restriction / Election in this matter.

## 5. Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph

The Office rejects claims 32-46 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office asserts that the claims "merely recite[] a use without any active, positive steps delimiting how this use is actually practiced." Office Action, page 4.

Without acquiescing as to the merits of the Office's rejection, Applicants have amended claims 32-46 to recite a method comprising ***at least one active step***. The Office's rejection is thus moot. Applicants respectfully request withdrawal of the indefiniteness rejection, and allowance of claims 32-46.

## 6. Rejection of the Claims Under 35 U.S.C. § 101

The Office rejects claims 32-46 under 35 U.S.C. § 101, alleging that the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process. Office Action, pages 4-5.

Without acquiescing as to the merits of the Office's rejection, Applicants amend claims 32-46 to recite a method comprising ***at least one active step***. Accordingly, the rejection under 35 U.S.C. § 101 is moot. Applicants respectfully request withdrawal of the rejection and allowance of claims 32-46.

## 7. Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph

The Office rejects claims 17-46 under 35 U.S.C. § 112, first paragraph, alleging that the specification does not reasonably provide enablement for the prevention of negative effects of

liver diseases. Office Action, page 5. When conducting a multi-factor analysis according to *Wands*, the Office alleges:

1) the present invention is directed to a method for ***preventing*** liver diseases;
2) the scope of the method claims includes the ***prevention*** of liver diseases;
3) the Specification does not provide experimental evidence or mechanism of action for supporting the ***prevention*** of liver diseases;
4) the Specification and the Examples of the application do not provide any guidance in terms of ***preventing*** liver diseases;
5) the specification does not provide working examples for ***preventing*** liver diseases; and
6) the quantity of experimentation would be an undue burden to a skilled artisan.

The Office also asserts "unpredictability of preventing cardiovascular disease." Office Action, page 7. The Office must have meant "unpredictability of preventing liver diseases."

Without acquiescing as to the merits of the Office's rejection, Applicants amend the claims to no longer recite "preventing" or "preventive." The rejection under 35 U.S.C. § 112, first paragraph, is thus moot. Applicants respectfully request withdrawal of the enablement rejection and allowance of claims 17-46.

## 8. Rejection of the Claims Under 35 U.S.C. § 103(a)

The Office rejects claims 17-46 under 35 U.S.C. § 103(a) as being unpatentable over **Bistrian** et al., U.S. Patent No. 5,320,846 [hereinafter "Bistrian"] and **Akimoto** et al., U.S. Published Application No. 2004/0171127 [hereinafter "Akimoto"].

Bistrian is relied upon by the Office for teaching a method of treating patients with splanchnic disorders, such as liver or gut dysfunction. Office Action, page 9. The disorder or dysfunction may include cancer, ischemia, trauma, sepsis, malnutrition, liver surgery, hepatitis, or liver transplant. *Id.* The disclosed nutritional diet allegedly comprises a lipid source, which may include an omega-3 or omega-9 fatty acid. *Id.*

Akimoto is relied upon by the Office for teaching a method of preparing an omega-9-constituted fat from *Mortierella*. Office Action, pages 9-10. The omega-9-constituted fat is allegedly useful for treating and preventing arteriosclerosis, thrombosis and cancer. Office Action, page 10.

The Office asserts that it would have been *prima facie* obvious to combine the teaching of Bistrian and Akimoto to produce a method of preventing or ameliorating liver diseases by administering an omega-9 fatty acid. *Id.* The Office asserts that both compositions of Bistrian and Akimoto are (1) taught in the prior art, and (2) useful for the same purpose. *Id.* The "same purpose" apparently refers to cancer treatment. The Office then asserts "one would have a reasonable expectation of success given that Barnsley and Kamijo provide a detailed blueprint for making the liquid drug preparation, and the steps of which are routine to one of ordinary skill in the art." Office Action, page 11.

A finding of obviousness under 35 U.S.C. § 103 requires a determination of the scope and content of the prior art, the differences between the invention and the prior art, the level of ordinary skill in the art, and whether the differences are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966); and *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 82 U.S.P.Q.2d 1385 (2007). Both the suggestion of the claimed invention and a predictable expectation of success must be in the prior art, not in the disclosure of the claimed invention. *In re Dow Chem. Co.*, 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). Additionally, "obviousness requires a suggestion of ***all*** limitations in a claim." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342, 68 U.S.P.Q.2d 1940, 1947 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974) (emphasis added). Furthermore, one common inquiry of any obviousness test post-*KSR* is whether a skilled artisan would have had a reasonable expectation of success to practice the claimed invention. *Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in View of the Supreme Court Decision in* KSR International Co. v. Teleflex Inc., 72 Fed. Reg. 57,528.

Applicants traverse the rejection to the extent it may be applied to the amended claims. First, Bistrian's lipid component does not function to treat liver dysfunctions, because the omega-9 fatty acid is ***not*** the active component, but rather adenosine is the active component. Thus, Bistrian is not considered for all that it teaches ***as a whole***. Bistrian teaches a treatment for clinical disorders characterized by depletion of metabolic energy sources. *See e.g.*, Abstract of Bistrian. For example, Bistrian states:

> The present invention generally relates to providing adenosine, or one of its related nucleosides, in an enteral feeding regimen which enables splanchnic tissues to more rapidly generate ATP, or other related nucleotides, during or following shock or trauma, including post-transplant situations.

*See* Bistrian, col. 3, lines 63-68. Additionally, Bistrian describes the "***effective***" component of the diet as adenosine.

> The invention includes a total enteral nutrition diet having nutritionally ***acceptable amounts*** of a lipid source, a protein source, a carbohydrate source, a vitamin source, and a mineral source, and an ***effective amount*** of adenosine to achieve normal metabolic levels of ATP and/or its precursors in ATP deficient organs of a recipient host.

*See also* Abstract of Bistrian (emphasis added). Bistrian thus fails to teach or suggest using an omega-9 fatty acid or an omega-9-constituted fat as the active component to ameliorate liver diseases associated with hepatopathy.

Second, Akimoto does not teach liver diseases. Akimoto thus fails to teach or suggest using an omega-9 fatty acid or an omega-9-constitiuted fat as the active component to ameliorate liver diseases associated with hepatopathy.

The Office next asserts that it would have been obvious to combine Bistrian and Akimoto, because "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose." Office Action, page 10 (citing *In re Kerkhoven*, 626 F.2d 846, 850, 205 U.S.P.Q. 1069, 1072 (C.C.P.A. 1980)). The Office presumably refers to cancer treatment as the same purpose taught by Bistrian and Akimoto.

Applicants disagree. The Office mischaracterizes Akimoto and then misapplies *Kerkhoven*. Akimoto discloses that an omega-3 or omega-6 fatty acid is useful for treating and preventing cancer. *See* Akimoto, ¶¶ [0004], [0014]. However, Akimoto does not disclose the anti-cancer function of an omega-9 fatty acid. Akimoto in fact discloses that an omega-9 fatty acid may function as an anti-inflammatory, anti-allergic, or anti-rheumatic agent. *See* Akimoto, ¶ [0015]. Accordingly, Bistrian and Akimoto cannot overlap in their teachings, because Akimoto simply fails to teach the anti-cancer function of an omega-9 acid. The Office's application of *Kerkhoven* is thus unsupported absent a showing of the "same purpose."

The amended claims recite ameliorating liver diseases associated with hepatopathy using an omega-9 fatty acid or a compound having an amega-9 fatty acid as a constituent fatty acid as the active component. As discussed above, neither Bistrian nor Akimoto, nor the combination of the two, teaches or suggests using an omega-9 fatty acid or an omega-9-constituted fat as an active component to ameliorate liver diseases as claimed. Accordingly, the references when viewed alone or in combination fail to suggest the claims as amended. Additionally, failure to teach or suggest all the elements also means that there can be no predictable expectation that the presently recited and claimed combination would have worked.

Furthermore, the Office alleges that a reasonable expectation of success exists based on Barnsley and Kamijo. Office Action, page 11.[1] But for one sentence, Applicants have been unable to identify these references either on a PTO-892 form or in PAIR. Applicants cannot adequately respond to whether the references indeed support a reasonable expectation of success absent their provision *and* an explanation of *why* they apply. Applicants respectfully request clarification with the Office's next communication. Applicants note that if provided, the next action cannot be made final with regard to this aspect of the rejection, regardless of Applicants' amendment to the claims.

Based on the above arguments, no *prima facie* case of obviousness can be adduced with regard to the claims either as amended or unamended. Accordingly, Applicants respectfully request withdrawal of the obviousness rejection and allowance of claims 17-46.

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1 "Finally, one would have a reasonable expectation of success given that Barnsley and Kamijo provide a detailed blueprint for making the liquid drug preparation, and the steps of which are routine to one of ordinary skill in the art."

## CONCLUSION

Should the Office have any questions or comments regarding Applicants' amendments or response, she is asked to contact Applicants' undersigned representative at (202) 842-8821. Please direct all correspondence to the below-listed address.

In the event that the Office believes that there are fees outstanding in the above-referenced matter and for purposes of maintaining pendency of the application, the Office is authorized to charge the outstanding fees to Deposit Account No. 50-0573. The Office is likewise authorized to credit any overpayment to the same Deposit Account Number.

Respectfully Submitted,

Date: September 28, 2009 By: _____

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